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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LOEB, BRONWEN

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 04/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/029,579

Applicant(s)

LANDEGREN, ULF

Examiner

Bronwen M. Loeb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

This action is in response to the Request for Continued Examination (RCE) received 17 January 2002. The RCE, requesting consideration of the amendment filed 7 August 2001, was proper. The amendment filed 7 August 2001, in which claims 1-6 were cancelled and new claims 8-12 were presented, has been entered in the case.

Claims 7-12 are pending.

Specification

1. The abstract from parent PCT/SE96/01119 has been entered in the specification.

Sequence Compliance

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because the sequence in the sequence listing does not match the sequence in the specification. Specifically, the four biotinylated cytosines in the sequence disclosed on p. 7 of the specification are not included in SEQ ID No. 1. As set forth in 37 CFR 1.8229b), a modified nucleotide base which does not appear in WIPO Standard ST.25 (1998), Appendix 2, Tables 1 and 3, should be listed as "n" in the sequence with the appropriate further information provided in the Features section.

Applicants are required to comply with all of the requirements of 37 CFR 1.821 through 1.825. Any response to this office action that fails to meet all of these

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requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. 1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

A reply to a notice to comply with the sequence rules should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office because mail sent to this zip code is destined for irradiation. Computer readable formats, such as disks and CD's, are destroyed as a result of the irradiation process. The following information is also provided on the website.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio
(<http://www.uspto.gov/ebs/efs/downloads/documents.htm>
>, EFS Submission User Manual - ePAVE)

2. Mailed to:
U.S. Patent and Trademark Office
Box Sequence, P.O. Box 2327
Arlington, VA 22202

3. Mailed by Federal Express, United Parcel Service or other
delivery service to:
U. S. Patent and Trademark Office
2011 South Clark Place
Customer Window, Box Sequence
Crystal Plaza Two, Lobby, Room 1B03
Arlington, Virginia 22202

4. Hand Carried directly to the Customer Window at:
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Crystal Plaza Two, Lobby, Room 1B03, Box Sequence,
Arlington, Virginia 22202

Response to Amendment

3. The rejection of claims 1-6 under 35 USC §112, first paragraph for lack of enablement has been withdrawn in view of Applicant's amendment.
4. Claim 7, and newly presented claims 8-10 and 12, stand rejected under 35 USC §102(b) as being anticipated by Nilsson et al (Science (1994) 265:2085-2088). The declaration under 37 CFR 1.132 originally filed 7 August 2001 is insufficient to overcome the rejection of claim 7 based upon Nilsson et al as set forth in the last Office action because: the Nilsson reference is prior art under 35 USC §102(b) and therefore cannot be removed as art by a declaration under 37 CFR 1.132. This is discussed in more detail below.

Response to Arguments

5. With regard to the rejection of claim 7, and newly presently claims 8-10 and 12, under 35 USC §102(b) as being anticipated by Nilsson et al, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant argues that as per 35 USC §365(b), the priority date of the instant application is 8 September 1995, the date the foreign parent application (Swedish National Application 9,503,117-5) was filed. This assertion is incorrect. As noted in the Advisory Action mailed 16 August 2001, the effective filing date of this application is the filing date of the PCT application, 6 September 1996. The right of priority in 35 USC §365(b) is "in accordance with the conditions and requirements of section 119(a) of this title...". 35 USC §119(a) concludes with "but no patent shall be granted on any

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application for patent for an invention which has been patented or described in a printed publication in any country more than one year ***before the date of the actual filing of the application in this country...*** (emphasis added). In other words, the relevant date for determining if a reference is 102(b) art is the filing date in the US, which in accordance with 35 USC §363, is the filing date of the PCT application.

Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is based on the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. §112, first paragraph "Written Description" Requirement published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). Claim 11 is drawn to a composition comprising a padlock probe wherein the end part further comprise a mutually chemically reactive compound. This is a genus claim in terms of any mutually chemical reactive compound. The specification mentions no examples of any mutually chemical reactive compounds. This disclosure is not deemed

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to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all mutually chemical reactive compounds based on the teachings in the specification. The specification does not provide a definition for this phrase nor are there any examples. It further is stated that this way of joining oligonucleotide ends has been previously used in the art (p. 6) however no references are cited. Therefore, the specification does not describe the claimed mutually chemical reactive compounds in such full, clear, concise and exact terms so as to indicate that Applicant has possession of these compounds at the time of filing the present application. Thus, the written description requirement has not been satisfied.

8. The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 11 and 12 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is vague and indefinite for reciting "said end parts further comprise a mutually chemically reactive compound". First, the specification does not define "a mutually chemically reactive compound" or provide any examples of one. Is it a self-reactive compound or does it refer to a pair of compounds which react with each other. In addition, it is unclear if the same compound is attached to each end part, or, if is a pair of compounds which are chemically reactive.

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Conclusion

Claims 7-12 are rejected. Claim 11 is free of prior art.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Tracey Johnson, Patent Analyst whose telephone number is (703) 305-2982.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

April 8, 2002



REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
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